Clinical Policy: Ubrogepant (Ubrelvy)

Reference Number: CP.PHAR.476
Effective Date: 06.01.20
Last Review Date: 05.20 Revision Log
Line of Business: Commercial, HIM, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Ubrogepant (Ubrelvy™) is a calcitonin gene-related peptide (CGRP) receptor antagonist.

FDA Approved Indication(s)

Ubrelvy is indicated for the acute treatment of migraine with or without aura in adults.

Limitation(s) of use: Ubrelvy is not indicated for the preventive treatment of migraine.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Ubrelvy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Migraines (must meet all)**:**

1. Diagnosis of migraine headaches;
2. Age ≥ 18 years;
3. Failure of at least TWO formulary $5HT_{1B/1D}$-agonist migraine medications (e.g., sumatriptan, rizatriptan, zolmitriptan) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. For requests for monthly quantities > 1 box of 6 tablets per month, member meets all of the following (a, b, and c):
   a. Failure of TWO oral migraine prophylactic therapies from different therapeutic classes, each for 8 weeks, unless clinically significant adverse effects are experienced or all are contraindicated *(see Appendix B)*;
      **Prior authorization may be required.*
   b. Failure of a 3-month trial of ONE CGRP inhibitor* used for migraine prophylaxis, unless clinically significant adverse effects are experienced or all are contraindicated *(see Appendix B);*
      **Prior authorization may be required.*
   c. Member is being treated by or in consultation with a neurologist, headache, or pain specialist;
5. Ubrelvy is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig™, Ajovy™, Emgality™);
6. Dose does not exceed 200 mg (2 tablets) per day and 8 days per month.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Migraines (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. For dose increase requests to quantities > 1 box of 6 tablets per month, member meets all of the following (a, b, and c):
   a. Failure of at least TWO oral migraine prophylactic therapies from different therapeutic classes, each for 8 weeks, unless clinically significant adverse effects are experienced or all are contraindicated *(see Appendix B)*;
      **Prior authorization may be required.*
   b. Failure of a 3-month trial of ONE CGRP inhibitor* used for migraine prophylaxis, unless clinically significant adverse effects are experienced or all are contraindicated *(see Appendix B);*
      **Prior authorization may be required.*
   c. Member is being treated by or in consultation with a neurologist, headache, or pain specialist;
4. Ubrelvy is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig™, Ajovy™, Emgality™);
5. If request is for a dose increase, new dose does not exceed 200 mg (2 tablets) per day and 8 days per month.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

5-HT: serotonin
AAN: American Academy of Neurology
CGRP: calcitonin gene-related peptide
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Abortive Migraine Therapy		
Drug Name	**Dosing Regimen**	**Dose Limit/Maximum Dose**
Triptans		
naratriptan (Amerge®)	One tablet (1 or 2.5 mg) PO at onset; can be repeated in 4 hours	5 mg/day
almotriptan (Axert®)	6.25 to 12.5 mg PO QD May repeat dose in 2 hours	25 mg/day
frovatriptan (Frova®)	2.5 mg PO QD May repeat dose in 2 hours	7.5 mg/day
sumatriptan (Imitrex® nasal spray)	One spray (5 to 20 mg) at onset into one nostril; can be repeated in 2 hours	40 mg/day
sumatriptan (Imitrex®)	One tablet (25 to 100 mg) PO at onset; can be repeated in two hours	200 mg/day
rizatriptan (Maxalt® /Maxalt MLT®)	One tablet (5 or 10 mg) PO at onset of migraine headache; can be repeated in two hours	30 mg/day
eletriptan (Relpax®)	20 or 40 mg PO QD May repeat dose in 2 hours	40 mg/dose 80 mg/day
zolmitriptan (Zomig®/Zomig® ZMT)	1.25 or 2.5 mg PO QD May repeat dose in 2 hours	5 mg/dose 10 mg/day

Prophylactic Migraine Therapy		
Drug Name	**Dosing Regimen**	**Level of Evidence***
Antiepileptic Drugs*		
divalproex sodium (Depakote®)	500 to 1,000 mg/day PO	Level A (AAN; AHS)
divalproex sodium ER (Depakote® ER)	500 to 1,000 mg/day PO	Level A (AAN; AHS)
topiramate (Topamax®)	100 mg/day PO	Level A (AAN; AHS)
Beta-Blockers		
metoprolol (Lopressor®)	200 mg/day PO	Level A (AAN; AHS)
propranolol (Inderal®)	80 to 240 mg/day PO	Level A (AAN; AHS)
timolol (Blocadren®)	20 to 30 mg/day PO	Level A (AAN; AHS)
atenolol (Tenormin®)	100 mg/day PO	Level B (AAN; AHS)
nadolol (Corgard®)	80 to 240 mg/day PO	Level B (AAN; AHS)

Prophylactic Migraine Therapy		
Drug Name	**Dosing Regimen**	**Level of Evidence***
Serotonin Reuptake Inhibitors		
venlafaxine XR (Effexor XR®)	150 mg/day PO	Level B (AAN; AHS)
Tricyclic Antidepressants		
amitriptyline (Elavil®)	30 to 150 mg/day PO	Level B (AAN; AHS)
CGRP Inhibitors*		
Aimovig (erenumab)	70 mg SC once a month; may be increased to 140 mg SC once a month	140 mg/month
Ajovy (fremanezumab)	225 mg SC once a month or 675 mg SC every 3 months	225 mg/month or 675 mg/3 months
Emgality (galcanezumab)	240 mg SC as a single loading dose, followed by 120 mg SC once a month	120 mg/month

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**American Headache Society (AHS) 2018, American Academy of Neurology (AAN) 2012: Level A: established efficacy, Level B: probably effective, Level C: possibly effective.*
***FDA approved.*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): concomitant use with strong CYP3A4 inhibitors
- Boxed warning(s): none reported

Appendix D: General Information

- The AAN recommends that prophylactic migraine medications should be considered if the patient experiences 2 or more attacks per month that produce aggregate disability of 3 or more days/month.
- The AAN and the National Headache Foundation recommend that prophylactic migraine medications should be considered if one or more of the following are present: greater than 2 migraine headaches per week; migraines cause significant impairment in daily routine even with abortive treatment; contraindication to, adverse effects, overuse or failure of abortive migraine medications, presence of uncommon migraine condition (e.g., basilar migraine); or patient requesting prophylactic therapy.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Migraines	50 or 100 mg PO, as needed. If needed, a second dose may be administered at least 2 hours after the initial dose. The maximum dose in a 24-hour period is 200 mg.	200 mg/day

VI. Product Availability

Tablets (package size 6, 8, 10, 12, 30): 50 mg, 100 mg

VII. References

1. Ubrelvy Prescribing Information. Madison, NJ: Allergan USA, Inc.; December 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211765s000lbl.pdf. Accessed January 23, 2020.
2. Dodick DW, Lipton RB, Ailani J, et al. Ubrogepant for the treatment of migraine. N Engl J Med 2019 Dec 5; 381:2230-41.
3. Lipton RB, Dodick DW, Ailani J, et al. Effect of ubrogepant vs placebo on pain and the most bothersome associated symptom in the acute treatment of migraine: the ACHIEVE II randomized clinical trial. JAMA 2019; 322(10):1887-98.
4. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59:1-18.
5. MICROMEDEX® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 27, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	02.04.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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